K111284

SECTION 5: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 17 2011

A. Submitter Information

Submitter's Name:	Ostial Corporation
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Date of Preparation:	May 5, 2011

B. Subject Device

Trade Name:	Flash-C PTCA Balloon Dilatation Catheter
Common/Usual Name:	PTCA Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous (21 CFR 870.5100, Product Code LOX)

C. Predicate Device Name(s)

Trade Name(s):	Maverick XL Monorail PTCA Dilatation Catheter
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous (21 CFR 870.5100, Product Code LOX)

D. Device Description:

The Flash-C PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The Flash-C PTCA Balloon Dilatation Catheter is a 0.014" guidewire-compatible, rapid exchange (RX) angioplasty balloon catheter with proximal anchoring. The Flash-C PTCA Balloon Dilatation Catheter uses a dual balloon design that features a compliant anchoring balloon that enables the operator to precisely position the catheter at aorto-ostial anatomies and prevent distal migration of the balloon during angioplasty. The second semi-compliant high pressure balloon allows for luminal dilatation.

E. Intended Use:

The Flash-C PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The Flash-C PTCA Balloon Dilatation Catheter and the predicate Maverick XL Monorail PTCA Dilatation Catheter have the equivalent intended use. Both are indicated for treatment of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The indication statement for the Flash-C PTCA Balloon Dilatation Catheter is a subset of the broader indication statement of the Maverick XL device, since the Maverick XL device is also indicated for the post delivery expansion of balloon expandable stents.

The Flash-C PTCA Balloon Dilatation Catheter and the predicate device both contain an inflatable semi-compliant balloon for dilation of obstructive lesions. The Flash-C PTCA Balloon Dilatation Catheter includes a second compliant balloon for locating and anchoring the device at ostial vessel locations.

The usable length of the Flash-C PTCA Balloon Dilatation Catheter is 135 cm which is a similar usable length as the predicate device (153cm). Both the proposed and predicate devices are offered in 5mm and

6mm balloon diameter sizes and approximately 20mm balloon lengths. The Maverick XL device is also available in additional diameters and lengths.

The Flash-C device and predicate device are substantially equivalent in terms of intended use, fundamental scientific technology, target population, and operating principles.

G. Performance Data:

The Flash-C PTCA Balloon Dilatation Catheter is identical in design, materials, and manufacturing to the Ostial Corporation's Flash PTA Balloon Dilatation Catheter, cleared by the FDA in 510(k) #K102482 on February 25, 2011. As such, in vivo and in vitro testing submitted in the Flash PTA 510(k) is applicable to the Flash-C PTCA device.

Biocompatibility testing was completed and submitted as part of the Flash PTA 510(k) #K102482. Requirements for biological evaluation of the device were based on ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

- ISO MEM Elution Assay
- ASTM Hemolysis Assay
- Complement Activation C3a and SC5b-9 Assay
- Thromboresistance Evaluation
- Pyrogen (LAL) Chromogenic
- Materials Mediated Pyrogen
- ISO Guinea Pig Maximization Sensitization
- ISO Acute Systemic Toxicity
- ISO Intracutaneous Reactivity

The Flash device was evaluated using the following in-vitro performance bench testing to confirm the performance characteristics:

- Balloon Crossing Profile
- Catheter Shaft Diameter
- Balloon Rated Burst Pressure (Angioplasty)
- Balloon Burst Volume (Anchoring)
- Angioplasty Balloon Compliance
- Balloon Inflation Time
- Balloon Deflation Time
- Angioplasty Balloon Fatigue
- Anchoring Balloon Fatigue
- Catheter Bond Strength
- Catheter Tip Pull Strength
- Catheter Torque Strength
- Simulated Use/Flexibility/Kink

Additional simulated use testing was performed on the Flash-C PTCA device to compare the performance to the current predicate device, the Maverick XL Monorail PTCA Dilatation Catheter. The testing demonstrated that the performance of the two devices is substantially equivalent.

In-vivo testing was completed on the Flash device using a swine model. A simulated angioplasty procedure was performed on test and control groups (the control group used the Sterling PTA Balloon Dilatation Catheter). Post procedure animals were survived and observed for a predetermined period to assess for downstream and cognitive effects.

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Flash-C PTCA Balloon Dilatation Catheter met the established specifications necessary for consistent performance according to its intended use.

H. Conclusions:

The Flash-C PTCA Balloon Dilatation Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, test protocols, and/or customer inputs. The Flash-C PTCA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ostial Corporation
c/o Mr. Mark Smutka
Clinical, Regulatory, and Quality Consultant
510 Clyde Avenue
Mountain View, CA 94043

AUG 17 2011

Re: K111284
Trade/Device Name: Flash-C PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty Catheter
Regulatory Class: Class II (two)
Product Code: LOX
Dated: July 27, 2011
Received: July 29, 2011

Dear Mr. Smutka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number: K111284

Device Name: Flash-C PTCA Balloon Dilatation Catheter

Indication For Use: The Flash-C PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111284